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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,121	03/24/2004	Joseph S.M. Peiris	V9661.0069	2460

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,121	PEIRIS ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/9/04, 9/15/04, 8/25/05*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *-18, 20, 21, 23, 25-32, 54-56, 58, 60, 62, 75, 77, 79, 81, 89-101, 108-111, 115, 117, 121-125, 130-133, 135-139, 144, 146, 151-154, 158-163 and 165-173* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-18,20,21,23,25-32,54-56,58,60,62,75,77,79,81,89-101,108-111,115,117,121-125,130-133,135-139,144,146,151-154,158-163 and 165-173.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, 27, 30, 89-94, 97, 98, 108, 109, 121, 122, 130, 131, 144, 160-162, 171, 172, drawn to virus *per se*, classified in class 435, subclass 235.1. See species election, below.

II. Claims 18, 20, 21, 23, 25, 26, 28, 29, 31, 32, 101, 115, 117, 125, 135, 146, 165, drawn to less than genome-length nucleic acid, classified in class 536, subclass 23.72 for example. See species election, below.

III. Claims 54-55, 56, 58, 60, 62, 75, 77, 79, 81, 95, 96, 136, 137,138, 139, 151, 152, 153, 154,158, 159, 166 167, 168, 169,170, 173, drawn to assay method, classified in class 435, subclass 5. See species election, below.

IV. Claims 99, 100, 110, 111, 123, 124, 132, 133, 163, drawn to isolated proteins, classified in class 530, subclass 350 for example. See species election, below.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and IV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, a virus does not overlap in scope with either an isolated subgenomic nucleic acid or an isolated

protein or protein extract, and the proteins and nucleic acids are different chemicals. The inventions are not obvious variants, because one cannot predict the structure of a subgenomic nucleic acid or an isolated subunit from the isolated virus per se, or predict all of the characteristics of the virus from a partial nucleotide sequence or a single subunit. Proteins and nucleic acids have long been established as patentably distinct products (In re Bell, 991 F.2d 781, 26 USPQ2d 1529; In re Deuel, 51 F.3d 1552, 1558-59, 34 USPQ2d 1210). Viruses, nucleic acids, and proteins have materially different modes of operation, function, and/or effect. The virus is capable of infection and self-replication, and the other products are incapable of this mode of operation. The nucleic acids and proteins have completely different functions and effects from each other and from the intact virus.

Inventions I and II are related to invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the virus as claimed can be used in a process of producing a killed virus vaccine, and the nucleic acids as claimed can be used in a process of expressing a single protein subunit.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Species election

Group I contains claims directed to the following patentably distinct species:

Non-attenuated viruses

Attenuated viruses.

The species are independent or distinct because attenuating mutations are highly unpredictable, and therefore an attenuated virus is not an obvious variant of a wild-type virus.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, FILL IN generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In group II, claims 18, 20, 21, 23, 25, 26, 28, 29, 31, 32, 101, 115, 117, 125, 135, 146, 165 are generic to the following disclosed patentably distinct species:

Each and every nucleic acid which does not contain a substantial common sequence with another nucleic acid constitutes a patentably distinct species. Therefore, every 5-mer is distinct from every nonoverlapping 5-mer, but not distinct from the overlapping 45-mer, 100-mer, 500-mer, etc. There are an astronomical number of disclosed species.

The species are independent or distinct because they are products which share an alleged common utility of usefulness as probes and/or primers but the common utility is not linked to a substantial common structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, each nonoverlapping nucleic acid can identify a different region of the SARS genome that cannot be identified by the other nonoverlapping nucleic acids.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of nucleic acid, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Group III contains claims directed to the following patentably distinct species:

Detection using antibody

Detection using nucleic acid (species of nucleic acid must be elected also)

Detection using infected cell

The species are independent or distinct because each detection method uses materially different products and active steps to detect materially different substances.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 54-55, 151, 152, 158, 159 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In group IV, claims 99, 100, 110, 111, 123, 124, and 132, 133, 163 are generic to the following disclosed patentably distinct species:

Each and every polypeptide which does not contain a substantial common sequence with another polypeptide constitutes a patentably distinct species. Therefore, every subunit or nonstructural protein is distinct from every other nonoverlapping subunit or nonstructural protein. There are a large of disclosed species in the Sequence Listing.

The species are independent or distinct because they are products which share an alleged common utility of immunogenicity but the common utility is not linked to a substantial common structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, each different polypeptide induces functionally distinct antibodies, which may vary in whether or not they react with the virion, whether or not they have neutralizing activity, which interfere with different biological activities of the virus.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of nucleic acid, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

A telephone call and fax of a draft of this restriction requirement was made to Charles E. Miller on 4/18/2006 to request an oral election to the above restriction requirement, but did not result in an election being made. Izumi Yokoyama (for attorney Miller) indicated that the client's overseas agent was not available to make the election.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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4/20/06

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER